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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/853,526	08/27/2001	Daniel Cohen	GEN-T111XC3D1	7147

7590 11/19/2002

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EXAMINER	
YAEN, CHRISTOPHER H	
ART UNIT	PAPER NUMBER
1642	14

DATE MAILED: 11/19/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/853,526	COHEN ET AL.	
	Examiner	Art Unit	
	Christopher H Yaen	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 July 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *50-61* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *50-61* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

1. The examiner of the application has changed. This case has now been transferred as of 8/26/02. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Christopher Yaen, Group Art Unit 1642.

Election/Restrictions

2. Applicant's election of group II (claims 10 and 42) in Paper No. 13 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

It is noted that the applicant has canceled claims 10 & 42 and has furnished a secondary preliminary amendment, which newly adds claims 50-61. Claims 50-61 are drawn to an invention not originally presented in the instant application. However, since the newly added claims constitutes a single invention, a first action on the merits follows.

Therefore, claims 5-8, 10, 13, 41, and 42 have been canceled without prejudice, claims 50-61 are pending and are examined on the merits.

Claim Rejections - 35 USC § 101

3. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 50 and 54-57 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The antibody and/or polypeptide recited in

independent claim 50 and dependent claims 54 (polypeptide) 55-57 (antibody) as currently written read on proteins that occur in nature. The claims never recite that the antibody or the polypeptide has been isolated and further indicates that the antibody and polypeptide are simple obtained from biological samples. Clearly, the antibody and/or polypeptide therefore exist in nature and fails to meet the requirements set forth in 35 USC 101.

4. Claims 50-61 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific asserted utility or a well established utility.

Claims 50-61 are drawn to a method of binding an antibody to PG1 polypeptide, wherein the disclosed utility is drawn to ELISAs or RIAs. However, neither the specification nor any art of record teaches what the protein is or how it functions. Furthermore, the specification has not associated this PG1 polypeptide with any specific disease or established any involvement in the etiology of any specific disease. It is noted that Xu *et al* (Am. J. Hum. Genet. 2001;69:341-350) begins to evaluate the possible role of PG1 with prostate cancer, but has not yet specifically associated nor delineated the role of PG1 and prostate cancer. Because this is an initial attempt to equate PG1 gene with prostate cancer, one can not be certain whether this PG1 gene is indeed associated with prostate cancer. Further, there is no evidence that the method of detecting the polypeptide in ELISAs or RIAs is even possible because there is no evidence that supports that the polypeptide to which the instant invention proposes to detect even exist or is expressed, because the prior art has not yet defined this protein. (ref saying mrna and protein are not equvalent)

In addition, even ***if*** the polypeptide of the instant invention can be defined and associated with a specific disease, the embodiments of the instant invention do not specifically associated the method of ELISA or RIA with a specific purpose. The proposed utilities are drawn to a broad classification of procedures that can be used for any protein/polypeptide. There is no specific goal associated with the proposed methods. For example, if the antibody binds to the polypeptide, what useful information will be achieved upon binding? Because there is a lack of absolute information concerning this PG1 gene, the information obtained from these methods is difficult to interpret and apply.

Therefore, given the uncertainty of the PG1 gene product, the lack of association with a specific disease, and the unspecific nature of the proposed utilities of the polypeptide and antibodies for that polypeptide, one cannot specifically utilize the instant invention with a specific purpose. Furthermore, one of skill in the art would be forced to experiment given the unpredicatable nature given that the utility cannot be fully assessed.

Claims 50-61 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Claim Rejections - 35 USC § 112

5. Claims 50-61 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to

reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The written description in this case only sets forth SEQ ID NO: 4, 5, or 70 and therefore the written description is not commensurate in scope with the claims which read on peptide fragments or peptide comprising at least 8 amino acids of SEQ ID NO. 4,5, or 70.

Vas-Cath Inc. V. Mahurkar, 19 USPQ2d 1111, clearly states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed*." (See page 1117). The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (*See Vas-Cath* at page 1116).

Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 USC 112 is severable from its enablement provision (see page 115).

With the exception of SEQ ID NO:4,5, or 70, the skilled artisan cannot envision the detailed structure of the encompassed polypeptides which include at least 8 amino acids of SEQ ID No: 4,5,or 70. Adequate written description requires more than a mere statement that it is part of the invention and a reference to a potential method of isolating it. The amino acid sequence itself is required. See *Fiers v. Revel*, 25 USPQ 2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. V. Chugai Pharmaceutical Co. Lts.*, 18 USPQ2d 1016. Although these court findings are drawn to DNA art, the findings are clearly applicable to the claimed proteins.

Furthermore, although drawn specifically drawn to the DNA art the findings of *The Regents of the University of California v. Eli Lilly* (43 USPQ2d 1398-1412) are clearly applicable to the instant rejection. The court held that a generic statement which defines a genus of nucleic acids by only their functional activity does not provide an adequate written description of the genus. The court indicated that while Applicants are not required to disclose every species encompassed by a genus, the description of a genus is achieved by the recitation of a representative number of DNA molecules, usually defined by a nucleotide sequence, falling within the scope of the claimed genus. At section B(1), the court states that "An adequate written description of a DNA...'requires a precise definition, such as by structure, formula, chemical name, or physical properties', not a mere wish or plan for obtaining the claimed chemical invention".

No disclosure, beyond the mere mention of sequences representing at least 8 amino acids of SEQ ID No: 4,5, or 70 is made in the specification. This is insufficient to support the generic claims as provided by the Interim Written Description Guidelines published in the June 15, 1998 Federal Register at Volume 63, Number 114, pages 32639-32645.

Therefore only SEQ ID No: 4,5, or 70 meet the written description provision of 35 USC 112, first paragraph.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher H Yaen whose telephone number is 703-305-3586. The examiner can normally be reached on Monday-Friday 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa can be reached on 703-308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Christopher Yaen
Art Unit 1642
September 27, 2002

Brenda Brumback

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SUPERVISORY PATENT EXAMINER
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